510(k) Summary

as required by 21 CFR Part 807.87(h)

JAN 29 2013

Identification of the Submitter

Submitter: M. Alaine Medio, RAC
PET and PCS Regulatory Projects Manager
Siemens Medical Solutions USA, Inc.
Molecular Imaging
810 Innovation Drive
Knoxville, TN 37932

Telephone Number: (865)218-2703

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Date of Submission: December 4, 2012

Identification of the product

Device Proprietary Name: Biograph mCT Family of PET/CT Systems

Common Name: Positron Emission Tomography (PET) System
Computed Tomography (CT) System

Classification Name: Emission Computed Tomography System per 21 CFR 892.1200
Computed Tomography X-Ray System per 21 CFR 892.1750

Product Code: 90 KPS and 90 JAK

Classification Panel: Radiology

Device Class: Class II

Marketed Devices to which Equivalence is claimed

Device	Manufacturer	510(k) Number
Biograph mCT-X and mCT-S	Siemens Medical Solutions USA, Inc	K113448

Device Description:

The Biograph mCT family systems are combined multi-slice X-Ray Computed Tomography and Positron Emission Tomography scanners. These systems are designed for whole body oncology, neurology and cardiology examinations. The Biograph mCT systems provide registration and fusion of high-resolution metabolic and anatomic information from the two major components of each system (PET and CT). Additional components of the system include a patient handling system and acquisition and processing workstations with associated software.

Biograph mCT software is a command based program used for patient management, data management, scan control, image reconstruction and image archival and evaluation. All images conform to DICOM imaging format requirements.

The updates to the Biograph mCT systems which are the subject of this application are considered substantially equivalent to the commercially available Biograph mCT software. Major modifications to the family of systems include:

- Updated 510(k) cleared CT is used compared to the CT used in the predicate PET/CT system (K113448);
- Updated gantry control buttons, and patient call button;
- Updated computer hardware;
- Updated software including:
    - updated operating system;
    - additional user configurable options and workflows
    - cardiac gating updates to provide for improved gating characteristics.;
    - updated workflows for ease of use; and
    - improvements in image quality.
- The new Biograph mCT capitalizes on list mode acquisition and positional information. Combined with the latest generation computer electronics it enables to continually take counts and reconstruct image data, providing a real-time display of the data flow as reconstructed.

Performance Testing:

Performance testing for the CT subsystem was included in the original premarket notification for the CT subsystems and there have been no changes affecting this testing.

PET Testing in accordance with NEMA NU2:2007 was conducted on two different configurations of the Biograph mCT systems, a 3 ring version and a 4 ring version.

Performance Criteria	Results	Acceptance
Transverse Resolution FWHM @ 1 cm	Pass	</= 6.5 mm
Transverse Resolution FWHM @ 10 cm	Pass	</= 6.5 mm
Axial Resolution FWHM @ 1 cm	Pass	</= 6.0 mm
Axial Resolution FWHM @ 10 cm	Pass	</= 6.5 mm
Sensitivity @435 keV LLD	Pass	>/= 4.0 cps/kBq (3R) >/= 8.5 cps/kBq (4R)
Count Rate peak NECR	Pass	86 kcps @ 36 kBq/cc (3R) 140 kcps@25 kBq/cc (4R)
Count Rate peak trues	Pass	280 kcps @ 42 kBq/cc (3R) 450 kcps @ 42 kBq/cc (4R)
Count Rate bias (mean)	Pass	<= 5%
Scatter Fraction	Pass	<40%

All Performance testing met the predetermined acceptance values.

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Risk Management is ensured via a risk analysis in compliance with ISO 14971 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product.

Siemens Medical Solutions, USA Inc. adheres to recognized and established industry standards such as IEC 60601-1 series and 21 CFR 1020.30 and 21 CFR 1020.33 to minimize electrical, mechanical and radiation hazards.

Verification and validation of Siemens systems is performed in accordance with documented procedures, design and code reviews, test plans and specifications. Traceability of the requirements specified in the requirement specifications and functional specifications is ensured during component integration, software validation and system testing.

Indications for Use:

The Siemens Biograph mCT systems are combined X-Ray Computed Tomography (CT) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information.

The CT component produces cross-sectional images of the body by computer reconstruction of X-Ray transmission data from either the same axial plane taken at different angles or spiral planes taken at different angles. The PET subsystem images and measures the distribution of PET radiopharmaceuticals in humans for the purpose of determining various metabolic (molecular) and physiologic functions within the human body and utilizes the CT for fast attenuation correction maps for PET studies and precise anatomical reference for the fused PET and CT images.

The system maintains independent functionality of the CT and PET devices, allowing for single modality CT and / or PET diagnostic imaging.

These systems are intended to be utilized by appropriately trained health care professionals to aid in detecting, localizing, diagnosing, staging and restaging of lesions, tumors, disease

and organ function for the evaluation of diseases and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer. The images produced by the system can also be used by the physician to aid in radiotherapy treatment planning and interventional radiology procedures.

Statement regarding Substantial Equivalence:

There have been no changes implemented in the modifications to the Biograph mCT that impact either the fundamental technology or the indications for use. The Biograph mCT with the modifications outlined in this Premarket Notification is substantially equivalent to the currently commercially available predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

JAN 29 2013

Ms. Alaine Medio, RAC
Official Correspondent
Siemens Medical Solutions USA, Inc - Molecular Imaging
810 Innovation Drive
KNOXVILLE TN 37932

Re: K123737
Trade/Device Name: Biograph mCT Family
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS and JAK
Dated: January 9, 2013
Received: January 10, 2013

Dear Ms. Medio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123737

Device Name: Biograph mCT Family

Indications for Use:

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Prescription Use __X__ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara 2013.01.29 18:22:16 -05'00'

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k)____**K123737**_____